**REMARKS**

Applicants' attorney is appreciative of the interview granted by the Examiner on October 12, 2004. At that interview, arguments were presented relating to all rejections of record.

The Office action has pointed out that Claims 78 through 86 are withdrawn from consideration based on the response to the restriction requirement mailed on December 31, 2001. However, based upon the renumbering of claims, it is unclear which claims should actually be cited as being withdrawn at this time; Claims 79-88 have been so designated. However, as examination is taking place based upon the generic and elected claims, and Applicants' arguments herein are based solely upon the generic claims, Applicants believe that rejoinder of the withdrawn claims would be appropriate should the generic claims be found to be allowable.

Claims 70 through 77 and 87 through 92 have been rejected under 35 USC 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors at the time the application was filed has possession of the claimed invention. The Office action alleges that the disclosure "lacks sufficient written description" for the claimed methods and has cited *Vas-Cath, Inc. v. Mahurkar*, 19 USPQ2d 1111, 1114 (Fed. Cir. 1991) and *In re Barker*, 194 USPQ 470, 473 (CCPA 1977).

With regard to the *Vas-Cath* case, Applicants note that the court therein stated that "[t]he cases indicate that the 'written description' requirement most often comes into play where claims not presented in the application when filed are presented thereafter" (page 1114), and *Vas-Cath* further states that "the applicant must also convey with reasonable clarity

to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (page 1117).

Applicants submit that there is no doubt that Applicants have met the requirements cited in *Vas-Cath*. The invention is directed to a method for improving dermis-epidermis cohesion comprising two steps, a first step of determining an area of the epidermis of a subject in which cohesion appears to be deficient, and a second step of applying to the area a composition containing ellagic acid or a derivative.

A method of cosmetic treatment for improving cohesion between dermis and epidermis by applying a composition containing ellagic acid and its derivatives was the subject of original Claim 16 of the present application as filed. Moreover, the invention is discussed in greater detail on page 3 of the present specification in which it is stated that these compositions make it possible to favor cohesion between the dermis and epidermis in persons "whose skin is atonic or loose." Thus, the relevant population for treatment has been identified clearly, and a number of compositions for application to the skin have been set forth in the examples section of the application. The objections cited in the Office Action go far beyond the requirement of a written description, requesting details pertaining to such methods of how the cohesiveness of the dermis-epidermis junction has improved, what the improvement is relative to and what process do Applicants have in possession a the time of filing. Clearly, the process in possession of Applicants at the time of filing is applying a cosmetic composition containing ellagic acid and its derivatives to the skin in areas where the cohesion appears deficient. Objection is also raised on

the basis that there is no working example, but no reason is given as to why a working example is necessary to satisfy the written description requirement. It is only necessary to show that Applicants were in possession of the invention at the time of filing, and certainly Applicants were in possession of the invention. The Office Action actually seems to focus more on problems with enablement, but once again, Applicants have fully enabled practicing the invention by setting forth particular compositions for application to the skin to accomplish the desired result.

Further, as regards the *Barker* case, one of ordinary skill in the art would realize that both claimed steps are part of the invention, based on the disclosure set forth on page 3 of the application.

The Office Action further states that there is no correlation between the exemplified demonstration of the activity of ellagic acid in increasing the proportion of collagen VII in a culture cell and the cohesion between dermis and epidermis layer using the claimed species. However, Applicants submit that none is required. If there is any doubt as to the utility of presently claimed compositions for the intended purpose such doubts should be expressed specifically, but not made in the form of a written description rejection which is not applicable to this situation.

Moreover, Applicants have set forth on pages 1 and 2 of the specification the state of the knowledge regarding the relationship between collagen VII and a lack of cohesion between dermis and epidermis. Applicants state that it is known that type VII collagen is the predominant constituent of anchoring fibrils associated with the basal membrane joining the dermis to epidermis. Further, the article by Chen et al

mentioned in the first complete paragraph on page 2 states that certain manifestations of skin aging, such as increased delicacy of the skin and reduced ability of the epidermis to repair itself, might be attributable to a decrease in synthesis of collagen VII in elderly subjects.

Taken as a whole, the specification clearly provides a rationale for alleging that improvement in the synthesis of collagen VII will improve the cohesion between dermis and epidermis, and further, Applicants have discovered that application of ellagic acid and its related compounds to the skin improves the synthesis of collagen VII.

Thus, it is clear that Applicants had possession of the claimed invention at the time the application was filed, and withdrawal of this rejection is requested.

Claims 70 through 77, 83 through 85 and 87 through 92 have been rejected under 35 USC 112, second paragraph, as being indefinite. The Office action alleges that claims directed to "improving dermis-epidermis cohesion in a subject" are ambiguous as there is no quantitative or qualitative measure. While there is clearly no quantitative measure given, the present specification provides a basis for a qualitative measure, for example as set forth on page 13, lines 22 through 26, which states that "[a]fter daily treatment for about six months, the skin becomes smoother, more supple and firmer." Thus, one of ordinary skill in the art would recognize that the treatments are effective, and no quantitative measurement is necessary in order to satisfy the requirements of 35 USC 112, second paragraph.

Withdrawal of this rejection is accordingly requested.

Claims 70 through 77, 87 through 90 and 92 have been rejected under 35 USC 102(b) as anticipated by Arima et al.

It is noted that Claims 70 and 93 have now been

specifically amended as discussed at the interview to recite that the first step of the claimed method is determining an area of the epidermis of a subject in which cohesion appears to be deficient *due to a deficiency in synthesis of collagen VII*.

The Arima et al patent discloses the use of compositions containing ellagic acid for applications to the skin for purposes of skin lightening and whitening. The patent discloses at column 1, lines 61 through 66, that ellagic acid series compounds have excellent skin lightening and whitening effect, and have no irritating or sensitizing properties and have good stability over time.

Arima et al does not disclose, however, that ellagic acid compounds increase synthesis of collagen VII or have any affect at all on dermis-epidermis cohesion.

As the undersigned argued at the interview, while a step corresponding to the second step of the claimed invention, applying ellagic acid containing composition to the skin, is disclosed in Arima et al (albeit for a different purpose), there is no step disclosed by Arima et al which corresponds to the first step of the claimed invention, "determining an area of the epidermis of the subject in which cohesion appears to be deficient." Thus, Arima et al is not interested in solving the problem of loose or atonic skin and does not disclose or suggest that applying ellagic acid compounds will solve that problem.

Further, as discussed at the interview, the recitation in the preamble of the present claims directing the invention to a "subject in need thereof" means that the population which would receive treatment according to the claimed invention is different from the population which would receive treatment according to Arima et al. While there may be some overlap in

such populations, where a person who needs skin lightening may also have areas of loose or atonic skin, there is no specific disclosure or suggestion in Arima et al of determining an area of a subject in which cohesion appears to be deficient due to a collagen VII deficiency.

Thus, Arima et al does not disclose or suggest the claimed invention, and withdrawal of this rejection is requested.

Claims 70 through 77 and 87 through 92 have been rejected under 35 USC 103(a) over Arima et al in view of Soler et al, Seguin et al and Bonte.

Solar et al has been cited to show the use of *pygenum africanum* in topical cosmetic and pharmaceutical compositions for various utilities including skin care associated with aging or acne, but does not teach a combination with ellagic acid. Sequin et al also relates to the use of *pygenum africanum* in cosmetic and pharmaceutical compositions, and Bonte discloses the use of topical extract compositions useful for improving collagen synthesis and dermal-epidermal cohesion.

However, none of the secondary references cited discloses or suggests that ellagic acid compounds are useful to improve collagen VII synthesis and to improve dermis-epidermis cohesion.

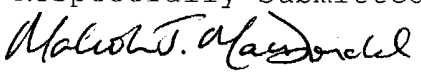
Moreover, it is noted that present Claim 93 recites specifically that the agent for increasing synthesis of collagen VII *consists essentially of* an ellagic acid compound, and thus excludes other compounds known for this purpose.

Withdrawal of this rejection is accordingly requested.

In view of the foregoing amendments and remarks, Applicants submit that the present application is now in condition for allowance. An early allowance of the

application with amended claims is earnestly solicited.

Respectfully submitted,



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